



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: QIU, Bo *et al.*

APPLICATION No.: 09/982,265

FILED: October 17, 2001

FOR: IMMUNOLOGICAL TEST KIT COMPRISING  
IMMUNOLOGICALLY INVISIBLE CARRIER CONJUGATED TO  
ONE OR MORE IMMUNOLOGICALLY REACTIVE  
SUBSTANCES

EXAMINER: MARY CEPERLEY

ART UNIT: 1641

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being deposited this day, August 4, 2004, with the United States Postal Service as Express Mail No. EL994146165US Post Office to Addressee addressed to Mail Stop RCE, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

AMY SHIELDS

**INFORMATION DISCLOSURE STATEMENT BEFORE FIRST OFFICE ACTION -**  
**37 C.F.R. § 1.97(b)(4)**

MS RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**1. Timing of Submission**

The information transmitted herewith is being filed before the mailing of a First Office Action after the filing of a request for continued examination (the information accompanies a request for continued examination). The references listed on the enclosed Form PTO-1449 (modified) may be material to the examination of this application; the Examiner is requested to make them of record in the application.

**2. Cited Information**

☒ Copies of the following references are enclosed:

- ☒ All cited references.
- ☐ References marked by asterisks
- ☐ The following:

☐ Copies of the following references can be found in parent U.S. Application No. :

- ☐ All cited references
- ☐ References marked by asterisks
- ☐ The following:

- ☐ This application was filed after 30 June 2003 and no copies of U.S. patents nor published applications are enclosed (See Notice of Deputy Commissioner Kunin on 11 July 2003).
- ☐ The following references are not in English. For each such reference, the undersigned has enclosed (i) a translation of the reference; (ii) a copy of a communication from a foreign patent office or International Searching Authority citing the reference, (iii) a copy of a reference which appears to be an English-language counterpart, or (iv) an English-language abstract for the reference prepared by a third party. Applicant has not verified that the translation, English-language counterpart or third-party abstract is an accurate representation of the teachings of the non-English reference, though, and reserves the right to demonstrate otherwise.
- ☐ All cited references  
☐ References marked by asterisks  
☐ The following:

**3. Effect of Information Disclosure Statement (37 C.F.R. § 1.97(h))**

This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

**4. Fee Payment (37 C.F.R. § 1.97(c)) or Certification (37 C.F.R. § 1.97(e))**

- ☒ No fee is believed due with this Information Disclosure Statement, which is filed under 37 C.F.R. § 1.97(b).
- ☐ Check enclosed for \$0.00.  
☐ Please charge the above fee(s) to Deposit Account No. **50-2586** this paper is provided in triplicate.
- ☐ Applicant submits that no fee is due in light of the following certification under 37 C.F.R. § 1.97(e) (check only one):
- ☐ In accordance with 37 C.F.R. § 1.97(e)(1), the undersigned hereby states that each item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to this filing of this statement; or

☐ In accordance with 37 C.F.R. § 1.97(e)(2), the undersigned hereby states that no item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c), more than three months prior to the filing of this statement.


☒ Please charge any underpayment for timely filing of this paper to Deposit Account No. **50-2586**.

**5. Patent Term Adjustment (37 C.F.R. § 1.704(d))**

☐ The undersigned states that each item of information submitted herewith was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this statement. 37 C.F.R. § 1.704(d).

Respectfully submitted,  
Perkins Coie LLP

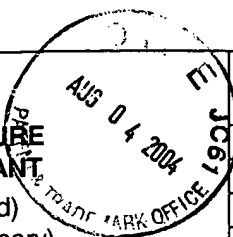
Dated: August 4, 2004

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Form PTO-1449 (Modified)  
(Use several sheets if necessary)



## COMPLETE IF KNOWN

Application Number 09/982,265  
Confirmation Number 8579  
Filing Date October 17, 2001  
First Named Inventor Qiu, Bo *et al*  
Group Art Unit 1641  
Examiner Name Mary Ceperley  
Attorney Docket No. 54114.8004.US00

Sheet 1 of 3

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	U.S. Patent or Application		Name of Patentee or Inventor of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Figures Appear
		NUMBER	Kind Code (if known)			
	C14	5,187,065		Schutzer	02/16/1993	
	C15	5,219,564		Zalipsky	06/15/1993	
	C16	5,455,027		Zalipsky	10/03/1995	
	C17	5,545,698		Barany	08/13/1996	

## FOREIGN PATENT DOCUMENTS

Examiner Initial	Cite No.	Foreign Patent or Application			Name of Patentee or Applicant of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Figures Appear	T
		Office	NUMBER	Kind Code (if known)				
	C18	WO	91 13630		United States of America	09/19/1991		
	C19	WO	97 42221		Statens Seruminstitut	11/13/1997		

## OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.	T
	C20	BARBOUR, "The Biological and Social Phenomenon of Lyme Disease", 260 Science 1610 (1993).	
	C21	BRUNNER, "Immune Complexes from Serum of Patients with Lyme Disease Contain Borrelia burgdorferi Antigen and Antigen-Specific Antibodies: Potential Use for Improved Testing", 182 J. of Infectious Diseases 534 (2000).	
	C22	BRUNNER, "Immunoglobulin M Capture Assay for Serologic Confirmation of Early Lyme Disease: Analysis of Immune Complexes with Biotinylated Borrelia burgdorferi Sonicate Enhanced with Flagellin Peptide Epitope", 36 J. Clin. Micro. 1074 (1998).	
	C23	BRUNNER, "New Method for Detection of Borrelia burgdorferi Antigen Complexed to Antibody in Seronegative Lyme Disease", 249 J. Immunol. Methods 185 (2001).	
	C24	BRUNNER, "Use of Serum Immune Complexes in a New Test that Accurately Confirms Early Lyme Disease and Active Infection with Borrelia burgdorferi", 39 J. Clin. Microbiol. 3213 (2001).	
	C25	ERVIN, "The Bell Tolls for the Infectious Diseases Clinician", 153 J. Inf. Dis. 183 (1986).	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application(s).

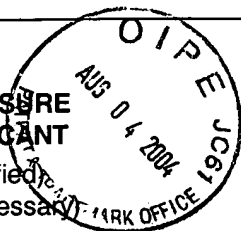
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Form PTO-1449 (Modified) (Use several sheets if necessary)				<b>COMPLETE IF KNOWN</b>	
				Application Number	09/982,265
				Confirmation Number	8579
				Filing Date	October 17, 2001
				First Named Inventor	Qiu, Bo <i>et al</i>
				Group Art Unit	1641
				Examiner Name	Mary Ceperley
Sheet	2	of	3	Attorney Docket No.	54114.8004.US00

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS			
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	C26	FRANK, "Spot Synthesis: An Easy Technique for the Positionally Addressable, Parallel Chemical Synthesis on a Membrane Support", 48 Tetrahedron 9217 (1992).	
	C27	GEYSEN, "Use of Peptide Synthesis to Probe Viral Antigens for Epitopes to a Resolution of a Single Amino Acid", 81 Proc. Natl. Acad. Sci. 3998 (1984).	
	C28	GILMORE, "Outer Surface Protein C (OspC), but not p39, is a Protective Immunogen Against a Tick-Transmitted <i>Borrelia burgdorferi</i> Challenge: Evidence for a Conformational Protective Epitope in OspC", 64 Infection and Immunity 2234 (1996).	
	C29	JUNGBLUT, "Proteomics in Human Disease: Cancer, Heart and Infectious Diseases", 20 Electrophoresis 2100 (1999).	
	C30	MAGNARELLI, "Cross Reactivity of Nonspecific Treponomal Antibody in Serologic Tests for Lyme Disease", 28 J. Clin. Microbiol. 1276 (1990).	
	C31	MATHIESEN, "The Dominant Epitope of <i>Borrelia garinii</i> Outer Surface Protein C Recognized by Sera from Patients with Neuroborreliosis Has a Surface-Exposed Conserved Structural Motif", 66 Inf. And Immun. 4073 (1998).	
	C32	MATHIESEN, "Peptide Based OspC Enzyme Linked Immunosorbent Assay for Serodiagnosis of Lyme Borreliosis", 36 J. Clin. Microbiol. 3474 (1998).	
	C33	QIU, "Studies on Polymers for Biomedical Applications: ...", (Dissertation, Oct. 1999) (unpublished).	
	C34	SCHNEIDER, "Prognostic B-Cell Epitopes on the Flagellar Protein of <i>Borrelia burgdorferi</i> ", 60 Inf and Immun. 316 (1992).	
	C35	SIGAL, "The Lyme Disease Controversy", 156 Arch. Intern. Med 1493 (1996).	
	C36	SIGAL, "Pitfalls in the Diagnosis and Management of Lyme Disease", 41 Arthritis & Rheumatism 195 (1998).	
	C37	SIGAL, "The Polymerase Chain Reacton Assay for <i>Borrelia burgdorferi</i> in the Diagnosis of Lyme Disease", 120 Annals Intern. Med. 520 (1994).	

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	C38	SIGAL, "A Vaccine Consisting of Recombinant <i>Borrelia burgdorferi</i> Outer-Surface Protein A to Prevent Lyme Disease", 4339 New Engl. J. Med. 216 (1998).	
	C39	SIMPSON, "Antibody to a 39-Kilodalton <i>Borrelia burgdorferi</i> Antigen (P39) as a Marker for Infection in Experimentally and Naturally Inoculated Animals", 29 J. Clin. Microbiol. 236 (1991).	
	C40	SIMPSON, "Nucleotide Sequence and Analysis of the Gene in <i>Borrelia burgdorferi</i> encoding the immunogenic P39 Antigen", 119 Fed. of Europ. Microbiol. Soc. Letters 381 (1994).	
	C41	SIMPSON, "Reactivity of Human Lyme Borreliosis Sera with a 39-Kilodalton Antigen Specific to <i>Borrelia burgdorferi</i> ", 28 J. Clin. Microbiol. 1329 (1990).	
	C42	YU, "Multi-Well ELISA Based on Independent Peptide Antigens for Antibody Capture", 198 J. Immunol. Meth. 25 (1996).	
	C43	YU, "Presentation of Peptide Antigens as Albumin Conjugates for Use in Detection of Serum Antibodies by Enzyme-Linked Immunosorbent Assay", 7 Bioconjugate Chem. 338 (1996).	

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